

SWalker: a robotic platform to aid rehabilitation following hip fracture

Submission date 19/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/02/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on hip fracture of elderly people. This paper presents the design and validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition.

Who can participate?

Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to walk again.

What does the study involve?

Participants were allocated to receive treatment using the SWalker or treatment as usual.

What are the possible benefits and risks of participating?

Benefits: The fundamental objective is to reduce patient mortality and recover the functional situation prior to hip fracture in elderly people who have suffered this pathology, and also that these achievements can be reached in the shortest possible time and at the lowest possible socio-economic cost, establishing the necessary strategies so that these benefits are maintained in the medium and long term.

Risks: No risks are foreseen.

Where is the study run from?

Albertia Servicios Sociosanitarios S.A. nursing homes (Spain)

When is the study starting and how long is it expected to run for?

March 2018 to April 2020

Who is funding the study?

1. Centro para el Desarrollo Tecnológico Industrial (CDTI) of the Ministry of Science and Innovation, Government of Spain
2. EDER/ Ministry of Science and Innovation/AEI) (Spain)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

SWALKERS17

Study information

Scientific Title

SWalker: a robotic platform for hip fracture rehabilitation

Acronym

SWalker

Study objectives

Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on the hip fracture of elderly people. This study presents the validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition in comparison with conventional rehabilitation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/01/2019, Fundación Jiménez Díaz Clinical Research Ethics Committee (Avda. de los Reyes Católicos, 2, 28040-Madrid, Spain; +34 915443720; ceic@fjd.es), ref: CPMP/ICH/135/95

Study design

Interventional non-randomized controlled trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Recovery from hip fracture in elderly people

Interventions

The performance of the SWalker platform was assessed at Albertia Servicios Sociosanitarios S.A. nursing homes.

Clinical validation was conducted with hip fracture patients.

The control group consisted of patients who followed conventional therapy, while the intervention group consisted of patients rehabilitated using SWalker. Allocation to groups was according to the choice of the participants. All patients had the possibility to use SWalker treatment.

Physiological parameters, and functional assessment scales such as FAC and Tinetti were collected at the beginning and at the end of the intervention. Gait recovery and rehabilitation process indicators were also gathered.

The total duration of the clinical validation was 15 months.

For each patient, the total duration of treatment was between 1 week and 1 month with the robotic platform.

For those patients who received conventional rehabilitation, treatment duration was up to 6 months in the most severe case. Patient follow-up was conducted in parallel with the clinical trials.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

SWalker

Primary outcome measure

1. Effectiveness of the device in injury recovery was measured with the variables "Number of physiotherapy sessions" and "Injury recovery time", which were quantified for each patient after the end of treatment (recovery defined as: no technical assistance or support staff needed to move around)
2. Degree of gait recovery measured by visual inspection by the clinical staff, assessing at the end of treatment whether the patient had fully recovered independent walking to perform their daily functional tasks (no technical assistance or support staff needed to move around), partially (requiring technical assistance such as a conventional walker, wheelchair, etc.) or not recovered walking at all

Secondary outcome measures

1. The quality of the patient's gait was measured with the Barthel index, Functional Ambulation Category (FAC), and Tinetti scale at the beginning and at the end of the treatment
2. The patients' nutritional and cognitive state was measured with the Mini Nutritional Assessment (MNA) and the Mini Examen Cognoscitivo (MEC) at the beginning and at the end of the treatment

Overall study start date

01/03/2018

Completion date

15/04/2020

Eligibility

Key inclusion criteria

1. Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to restore autonomous ambulation
2. Not received any other type of HF rehabilitation therapy

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

34

Total final enrolment

34

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

15/01/2019

Date of final enrolment

01/11/2019

Locations**Countries of recruitment**

Spain

Study participating centre

Albertia Servicios Sociosanitarios S.A.

Las Rozas De Madrid

Madrid

Spain

28222

Sponsor information**Organisation**

Albertia Servicios Sociosanitarios S.A.

Sponsor details

Las Rozas De Madrid

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

Centro para el Desarrollo Tecnológico Industrial (CDTI)

Funder Name

Ministry of Science and Innovation (Government of Spain)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/04/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (<https://zenodo.org/record/4549307#.YC6fPWhKhPZ>)

IPD sharing plan summary

Stored in repository